CORRECTED VERSION

(19) World Intellectual Property Organization

International Bureau





(43) International Publication Date 22 January 2004 (22.01.2004)

PCT

(10) International Publication Number WO 2004/006958 A1

(51) International Patent Classification7: 47/10, 38/18

A61K 47/02,

(21) International Application Number:

PCT/SI2003/000023

(22) International Filing Date:

14 July 2003 (14.07.2003)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

P-200200178

17 July 2002 (17.07.2002)

(71) Applicant (for all designated States except US): LEK PHARAMACEUTICALS D.D. [SI/SI]; Verokskova 57, 1526 Ljubljana (SI).

(72) Inventors; and

(75) Inventors/Applicants (for US only): VUKMIROVIC, Andreja [SI/SI]; Dergomaska 16, 1000 Ljubljana (SI). ROZMAN, Tanja [SI/SI]; Ul. Frankolovskih zrtev 11A, 3000 Celje (SI). SVETEK, Jelka [SI/SI]; Prusnikova 13, 1210 Ljubljana (SI). PARIS, Alenka [SI/SI]; Trzaska 121, 1000 Ljubljana (SI).

(74) Agent: KOSAK, Alenka; Intellectual Property Department, Lek Pharmaceuticals d.d., Verovskova 57, 1526 Ljubljana (SI).

(81) Designated States (national): AT, AU, BA, BG, BR, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, HR, HU, ID, IL, IN, JP, KR, LT, LU, LV, MK, MX, NO, NZ, PL, PT, RO, RU, SE, SG, SK, TR, UA, US, ZA.

(84) Designated States (regional): European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR).

Declaration under Rule 4.17:

of inventorship (Rule 4.17(iv)) for US only

Published:

with international search report

(48) Date of publication of this corrected version:

13 January 2005

(15) Information about Correction:

see PCT Gazette No. 02/2005 of 13 January 2005, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: STABLE PHARMACEUTICAL COMPOSITION COMPRISING ERYTHROPOIETIN

(57) Abstract: The present invention provides a new stable pharmaceutical composition of erythropoietin (EPO) that is stabilized with a combination of a poloxamer polyol and a polyhydric alcohol.

INTERNATIONAL SEARCH REPORT

1 JAN 2005

CLASSIFICATION OF SUBJECT MATTER PC 7 A61K47/02 A61K47/10 A61K38/18 According to International Patent Classification (IPC) or to both national classification and IPC B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61K Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) WPI Data, PAJ, CHEM ABS Data C. DOCUMENTS CONSIDERED TO BE RELEVANT Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. X EP 0 178 576 A (CHUGAI SEIYAKU KK, JP) 1.3-5.7.23 April 1986 (1986-04-23) 10-13, 19-22 claims 3,4 example 4 US 5 968 899 A (T.SEKINE ET AL.) 1-22 19 October 1999 (1999-10-19) claims examples Α US 5 656 289 A (Y.W.CHO ET AL.) 1-22 12 August 1997 (1997-08-12) claims Further documents are listed in the continuation of box C. Patent family members are listed in annex. Special categories of cited documents: *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the *A* document defining the general state of the art which is not considered to be of particular relevance invention earlier document but published on or after the International "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such docudocument referring to an oral disclosure, use, exhibition or ments, such combination being obvious to a person skilled in the art. document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 11/12/2003 2 December 2003 Name and mailing address of the ISA Authorized officer European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016

Scarponi, U



Internation No
PCT/SI 03/00023

0.46	NAME OF THE PARTY	101/31 03/00023	
	ation) DOCUMENTS CONSIDERED TO BE RELEVANT Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	
Calegory *	Oracion of document, with indication, where appropriate, or the relevant passages		
A A	WO 00 07627 A (JOHNSON & JOHNSON) 17 February 2000 (2000-02-17) claims examples	1-22	

INTERNATIONA SEARCH REPORT

information on patent family members

Internation Cation No
PCT/SI 03/00023

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
EP 178576	A	23-04-1986	JP	61091131 A	09-05-1986
El 170370	••		ΑT	47037 T	15-10-1989
		•	CA	1258628 A1	22-08-1989
			DE	3573533 D1	16-11-1989
			EP	0178576 A1	23-04-1986
			US	4879272 A	07-11-1989
US 5968899	Α	19-10-1999	EP	0803255 A1	29-10-1997
03 3300033	^	13 10 1000	WO	9533474 A1	14-12-1995
US 5656289	A	12-08-1997	AT	98480 T	15-01-1994
03 5050269	^	12 00 155,	AU	625498 B2	16-07-1992
			AÜ	4243289 A	05-04-1990
			AU	4341789 A	18-04-1990
			BG	60849 B1	31-05-1996
			CA	1339814 C	14-04-1998
			CZ	8905548 A3	13-01-1999
			DE	68911473 D1	27-01-1994
			DE	68911473 T2	05-05-1994
			DK	481989 A	30-03-1990
			EP	0366277 A2	02-05-1990
			ES	2060785 T3	01-12-1994
			FI	894637 A ,B,	30-03-1990
			MŌ	9003164 A2	05-04-1990
			HK	85596 A	24-05-1996
			HU	54033 A2	28-01-1991
			HU	9500585 A3	30-10-1995
			IE	63543 B1	17-05-1995
			JP	2218609 A	31-08-1990
			JP	2927835 B2	28-07-1999
				139641 B1	01-06-1998
			KR	17752 A	01-12-1993
			MX	893896 A	30-03-1990
			NO	230838 A	26-03-1991
			NZ	163635 B1	29-04-1994
			PL		30-03-1990
			PT	91850 A ,B 108219 B1	31-03-1994
			RO		27-11-1998
			RU Za	2122403 C1 8907437 A	26-06-1991
					04-09-2001
WO 0007627	Α	17-02-2000	US	6284234 B1	28-02-2000
			AU	5669599 A	17-02-2000
			CA	2339231 A1	11-07-2001
			CN	1303263 T	06-06-2001
			EP	1104280 A2	15-07-2003
			JP	2003521452 T	17-02-2000
			WO	0007627 A2	25-04-2002
			US	2002048558 A1	25-04-200Z